MFM NEO Mock Study Section Information NICHD Young Investigators Conference

At the Young Investigators meeting, there is a Mock Study Section. In this activity, we will be reviewing three actual grants as if we were a real study section. This session aims to provide you the experience of a NIH study section so you will understand the review process of the grants that you submit to NIH, the procedures, the specific evaluation criteria for different grant mechanisms (R03, R01, K23) and how the final score is determined.

In this packet are three grant applications. These are actual grant submissions that we have received permission from the applicants to use in this session. You will see that identifiers (names, institutions, identifying portions of the CV, etc.) have been removed to protect their identity. We have included all of the pages so that you can see what a grant application looks like.

Everyone in the session will be expected to have read and critiqued the grant. In addition there are primary, secondary and tertiary reviewers identified for each of the grants in the mock study section (see table below). If you are a primary, secondary or tertiary reviewer you will need to prepare to present your detailed review. We recommend that you work with your primary mentor or fellowship director on this review.

After the three primary reviewers, everyone will be asked for additional comments from your review of the application. We expect that all of you will participate in the review of each application, so please come prepared.

The Scientific Review Officer (SRO) will give an introduction and overview of the administrative aspects of the meeting at the start of the session. General guidelines for review as well as conflict of interest information will be presented in detail. The general agenda for each grant in the study section is as follows:

- Reviewer 1, 2, 3 all give their impact or priority scores (i.e. 1-9)
- Reviewer 1 gives their critique as per the attached instructions, ***please use the guidelines for the type of application (i.e. RO1 vs RO3 vs K23)***
- Reviewer 2 gives critique
- Reviewer 3 gives critique
- Statistician gives their critique
- General discussion – go around the table of reviewers (each to give input)
- Opinions from people outside the team/table
- Are there any Human subjects/animal concerns
- Are the gender and minority issues addressed?
- Are children included/addressed?
- Revote by Reviewers 1,2,3 for their scores
- Voting around the table (oral)
- Everyone in the room votes and records their score on sheet found in their packet

- Any budgetary concerns?

We will be reviewing three grant applications:
- RO1 application (Research grant application)
- RO3 application (Research small grant program)
- K23 application (Mentored patient oriented Research Career Development Award)

The titles of the grants are:
R01 –Initiation and Progression of Preterm Lung Injury with Ventilation
K23 - Postpartum Hemorrhage and Anemia: Epidemiologic and Cost-Effectiveness Analyses
R03 – Appetite Signaling and Gut Responses in Pregnancy

Reviewer Assignments

Group	SRA	Chair	Grant	Primary	Secondary	tertiary
1 (A-D)	Dr. Higgins	Dr. Martin	R01	Dr. Akangire Gangaram	Dr. Megan Berube	Dr. Robert Dietz
			R03	Dr. Sarah Anderson	Dr. Faranak Behinia	Dr. Danielle Berdahl
			K23	Dr. Stephanie Bryant	Dr. Natali Aziz	Dr. Sherman Chu
2 (E-L)	Dr. Miodovnik	Dr. Hay	R01	Dr. Elizabeth Enlow	Dr. Jina Lim	Dr. Melissa Kunkel
			R03	Dr. Jennifer Gilner	Dr. Rosemary Froehlich	Dr. Kayla Ireland
			K23	Dr. Christina Herrara	Dr. Gauri Luthra	Dr. Katie Forman
3 (M-P)	Dr. Reddy	Dr. Jain	R01	Dr. Christopher Nitkin	Dr. Margaret Nguyen l	Dr. Brighid O'Donnel
			R03	Dr. Audrey Merriam	Dr. Courtney Olsen-Chen	Dr. Sanjay Parwardhan
			K23	Dr. Lea Porche	Dr. Alicia McCarthy	Dr. Anuj Malik
4 (Q-Z)	Dr. Raju	Dr. Sadovsky	R01	Dr. Ariel Salas	Dr. Christina Sollinger	Dr. Noelle Young
			R03	Dr. Kara Marie Rood	Dr. Emma Rodriguez	Dr. Moeun Son
			K23	Dr. Luckey Reed	Dr. Sarah Lindsay Wood	Dr. Sushmita Yallapragada

Listed below are review guidelines links for these types of applications ***please use the correct one for each application

The announcements including review criteria for the various grants are at:

R01: http://grants.nih.gov/grants/guide/pa-files/PAR-11-222.html

R03: http://grants.nih.gov/grants/guide/pa-files/PA-11-262.html

K23: http://grants.nih.gov/grants/guide/pa-files/PA-10-060.html

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
Funding Opportunity Title	**Studies in Neonatal Resuscitation (R01)**
Activity Code	R01 Research Project Grant
Announcement Type	New
Related Notices	• September 26, 2014 - This PAR has been reissued as PA-14-350.
Funding Opportunity Announcement (FOA) Number	**PAR-11-222**
Companion FOA	PAR-11-223, R03 Small Grant Program PAR-11-224, R21 Exploratory/Developmental Grant
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.865
FOA Purpose	The purpose of this FOA is to stimulate research on a wide range of

	topics related to neonatal resuscitation. Possible topics may include, but are not limited to: fetal-neonatal transitional cardiovascular and pulmonary physiology, optimizing steps of resuscitation, management of third stage of labor and its effect on the fetus, resuscitation of children with malformations, and effect of resuscitation on long-term outcomes. Proposals can include epidemiological studies, studies utilizing fetal-neonatal animal models, computer or other information-technology-based simulations or study designs, clinical observational studies, analyzes of pre-existing national or regional datasets, prospective randomized controlled trials, or any combinations thereof. It is anticipated that the results from well conducted studies will enable translation of knowledge into evidence-based resuscitation practices ensuring a smooth neonatal transition for a healthy beginning, and lay a foundation for optimal short- and long-term outcomes for all newborn infants.

Key Dates

Posted Date	June 8, 2011
Open Date (Earliest Submission Date)	August 19, 2011
Letter of Intent Due Date	August 19, 2011, August 19, 2012, August 19, 2013
Application Due Date(s)	September 19, 2011, September 19, 2012, September 19, 2013, by 5:00 PM local time of applicant organization.
AIDS Application Due Date(s)	Not Applicable
Scientific Merit	February/March 2012, February/March 2013, February/March 2014

Review	
Advisory Council Review	May 2012, May 2013, May 2014
Earliest Start Date(s)	July 2012, July 2013, July 2014
Expiration Date	September 20, 2013
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

The purpose of this FOA is to stimulate research on a wide range of topics related to neonatal resuscitation. Possible topics may include, but are not limited to: fetal-neonatal transitional cardiovascular and pulmonary physiology, optimizing steps of resuscitation, management of third stage of labor and its effect on the fetus, resuscitation of children with malformations, and effect of resuscitation on long-term outcomes. Proposals can include epidemiological studies, studies utilizing fetal-neonatal animal models, computer or other information-technology-based simulations or study designs, clinical observational studies, analyzes of pre-existing national or regional datasets, prospective randomized controlled trials, or any combinations thereof. It is anticipated that the results from well conducted studies will enable translation of knowledge into evidence-based resuscitation practices ensuring a smooth neonatal transition for a healthy beginning, and lay a foundation for optimal short- and long-term outcomes for all newborn infants.

Background

In spite of major advances in neonatal care, there are many gaps in our understanding of the transitional fetal/neonatal physiology, and evidence-based neonatal resuscitation practices to facilitate a smooth transition from fetal to neonatal period. It has long been recognized that appropriate care of the newborn at birth is crucial for facilitating a smooth transition for infants born at all gestations. In term-healthy infants, such a transition will facilitate optimal temperature balance, mother-infant bonding, and good feeding, enabling the discharge of a healthy infant on time along with the mother. In sick infants, especially preterm, appropriate resuscitation methods (based on the need) enable stabilization of the cardiovascular and pulmonary systems, restoring adequate blood volume and preventing the adverse effects of marked deviation in acid-base balance, and oxygenation and ventilation parameters (avoiding hyper- and hypoxia, and hyper- and hypocarbia).

It has also been recognized that inappropriate resuscitation not only complicates recovery from already existing disease processes (e.g., respiratory distress due to immaturity, meconium aspiration syndrome, persistent pulmonary hypertension, diaphragmatic hernia), but also can cause adverse effects due to the act of resuscitation, per-se. The latter may manifest as pneumothorax, baro-trauma leading to prolonged ventilator dependency, injury to the developing brain, kidney, and other vital organs from deviations in oxygenation and abnormalities of acid-base status and circulating blood volume. Furthermore, due to their relative rarity, little research has gone into establishing the resuscitation practices for infants born with known congenital malformations such as congenital heart disease, diaphragmatic hernia, omphalocele and gastroschesis, oro-facial malformations, and mass lesions in the face and neck regions (e.g., cystic hygroma in the neck).

Scope

This FOA is an attempt to stimulate research in the wide topic area of neonatal resuscitation. The research proposals can be basic or applied, experimental or observational, and clinical or translational. The applicant need to state clearly how the findings from the proposed studies will improve specific issues related to resuscitation and how the knowledge will advance the field resulting in improved short- and long-term outcomes of newborn infants in the community.

Examples of the topic areas of interest are listed below. However, applicants can choose other topics that may be relevant to the broad category of neonatal resuscitation.

- Issues related to fetal-neonatal transitional physiology:
    - Fetal-to-neonatal transitional cardiovascular and pulmonary physiology; how do we optimize a smooth transition without having adverse consequences. In addition to measuring blood oxygen levels, one may need to study oxygen delivery (blood flow), its extraction and consumption in healthy as well as sick newborn infants under differing treatment conditions.
    - Fetal, transitional and neonatal physiology of PDA.
    - The effects of fetal and maternal medications on fetal and neonatal pulmonary vascular modeling.
- Biomarkers:
    - Biomarkers of fetal brain injury to provide accurate estimate of the timing, nature and extent of fetal brain injury for infants at risk for neonatal encephalopathy.
    - Biomarkers of fetal adaptation to chronic and acute fetal distress, and how such adaptations affect fetal brain metabolism, birth and transitional states.
    - Other easily detectable, user friendly, and reliable biomarkers of mitochondrial oxygen metabolism (e.g., metabolomics). These could be specific, or targeted towards a few but relevant components of the Krebs Cycle; urinary biomarkers such as alpha-ketoglutarate, fumarate or succinate in response to hypoxia/hyperoxia.
- Research on various steps during resuscitation,
    - Placental transfusion -- best time for clamping of the umbilical cord or milking of the umbilical cord; relative position of the infant to the plane of the placenta prior to cord clamping (or milking); use and value of such practices in normal as well as high-risk births.
    - Various concentrations of oxygenation during resuscitation; optimal target for oxygenation.
    - The comparison of different methods of providing continuous positive airway pressure (CPAP) during resuscitation and their effect on outcomes.

- Use of early versus rescue surfactant therapy; and maintaining a patent airway, use of CO2 detection; use of oro-pharyngeal airway; methods for successful intubation;
- Methods of providing assisted ventilation in the delivery room to minimize lung injury; assessing the benefits of prolonged lung inflations, inflation pressure tidal volume targets.
- Methods of supporting circulation (chest compression for CPR, etc.).
- CPR in special circumstances: multiple births; congenital malformations (omphalocele, gastroschesis, meningomyelocele; EXIT procedures etc.

- Fetal interventions:
  - Therapy for fetal distress that may protect the brain and facilitate birth and transition.
- Studies to demonstrate that good-resuscitation is prelude to optimal short- and long-term outcomes.
- Studies of environmental factors on outcome: temperature of the delivery room and its effect on preterm infants requiring resuscitation;
- Studies on the effects of maternal anesthesia and analgesia.
- Research on CPR education:
  - Developing evidence-based knowledge and evaluation of recent knowledge,
  - Practical approaches with training /teaching with mannequins, video recordings, etc.

Section II. Award Information

Funding Instrument	Grant
Application Types Allowed	New Renewal Resubmission Revision The OER Glossary and the SF 424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon NIH appropriations, and the submission of a sufficient number of meritorious applications.
Award	Application budgets are not limited, but need to reflect actual needs of the

Budget	proposed project.
Award Project Period	The total project period for an application submitted in response to this funding opportunity may not exceed 5 years.

NIH grants policies as described in the NIH Grants Policy Statement will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants
Eligible Organizations

Higher Education Institutions:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments

- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American tribal organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Organizations)

Foreign (non-U.S.) components of U.S. Organizations are allowed.

Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- Central Contractor Registration (CCR) – must maintain an active registration, to be renewed at least annually
- Grants.gov
- eRA Commons

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be completed by the application due date. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

NIH will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. NIH will not accept any application that is essentially the same as one already reviewed. Resubmission applications may be submitted, according to the NIH Policy on Resubmission Applications from the SF 424 (R&R) Application Guide.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the “Apply for Grant Electronically” button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

Descriptive title of proposed research
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions
Number and title of this funding opportunity

The letter of intent should be sent to:

Tonse N. K. Raju, MD
Pregnancy and Perinatology Branch (PPB)
Center for Developmental Biology and Perinatal Medicine (CDBPM)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
6100 Executive Boulevard, Room 4B03
Bethesda, MD 20892-7510
Rockville, MD 20852 (for express/courier service; non-USPS service)
Telephone: 301- 402-1872
Fax: 301-496-6790
Email: rajut@mail.nih.gov

Required and Optional Components

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for application submission. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed.

PHS 398 Research Plan Component

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan

Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix

Do not use the appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Foreign Organizations

Foreign (non-US) organizations must follow policies described in the NIH Grants Policy Statement, and procedures for foreign organizations described throughout the SF424 (R&R) Application Guide.

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov, the online portal to find and apply for grants across all Federal agencies. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement.

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically.

> **Important reminders:**
> All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.
>
> The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the Central Contractor Registration (CCR). Additional information may be found in the SF424 (R&R) Application Guide.
>
> See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Applications that are incomplete will not be reviewed.

Requests of $500,000 or more for direct costs in any year

Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact NIH program staff at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF 424 (R&R) Application Guide.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-10-115.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Human Subjects Protection and Inclusion Guidelines.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the Human Subjects Protection and Inclusion Guidelines.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by Center for Scientific Review (CSR), in accordance with NIH peer review policy and procedures, using the stated review criteria. Review assignments will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications, Following initial peer review, recommended applications will receive a second level of review by the National Advisory Child Health and Human Development Council. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to the DUNS, CCR Registration, and Transparency Act requirements as noted on the Award Conditions and Information for NIH Grants website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities. More information is provided at Award Conditions and Information for NIH Grants.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the NIH Grants Policy Statement.

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *NIH Grants Policy Statement*.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the NIH Grants Policy Statement for additional information on this reporting requirement.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Telephone 301-435-0714
TTY 301-451-5936
Email: GrantsInfo@nih.gov

eRA Commons Help Desk(Questions regarding eRA Commons registration, tracking application status, post submission issues)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov

Scientific/Research Contact(s)

Tonse N. K. Raju, MD
Pregnancy and Perinatology Branch (PPB)
Center for Developmental Biology and Perinatal Medicine (CDBPM)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
6100 Executive Boulevard, Room 4B03
Bethesda, MD 20892-7510
Rockville, MD 20852 (for express/courier service; non-USPS service)
Telephone: 301- 402-1872
Fax: 301-496-6790
Email: rajut@mail.nih.gov

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

Bryan S. Clark, MBA
Chief, Grants Management Branch

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
6100 Executive Boulevard
Bethesda, MD 20892-7510
Rockville, MD 20852 for courier/non-USPS service
Telephone: 301-435-6975
Email: clarkb1@mail.nih.gov

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts*. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Human Genome Research Institute (NHGRI) National Institute on Aging (NIA) National Institute on Alcohol Abuse and Alcoholism (NIAAA) National Institute of Allergy and Infectious Diseases (NIAID) National Institute of Biomedical Imaging and Bioengineering (NIBIB) *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) National Institute on Drug Abuse (NIDA) National Institute of Environmental Health Sciences (NIEHS) National Institute of Mental Health (NIMH) National Institute of Neurological Disorders and Stroke (NINDS) National Institute of Nursing Research (NINR)(No Longer Participating per NOT-NR-13-013)
Funding Opportunity Title	**NIH Small Research Grant Program (Parent R03)**
Activity Code	R03 Small Grant Program
Announcement Type	Reissue of PA-10-064
Related Notices	• August 2, 2013 - This PA has been reissued as PA-13-304. Use reissued PA for due dates of September 25, 2013 and beyond. • May 30, 2013 (NOT-OD-13-074) - NIH to Require Use of Updated Electronic Application Forms for Due Dates on or after September 25, 2013. Forms-C applications are required for due dates on or after September 25, 2013. • July 19, 2013 - See Notice NOT-NR-13-013. Notice of Change in Participation. • September 14, 2011 - See Notice NOT- DA-11-022. The

	National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) are issuing this Notice to encourage individuals interested in submitting applications for research on the economics of treatment and prevention services for drug and alcohol abuse to submit their applications using using the Parent R01, Parent R21 and Parent R03 Funding Opportunity Announcements. • August 12, 2011 – The Open Date has been changed from September 16, 2011 to August 12, 2011 to allow for immediate submission of applications. • July 13, 2011 - See Notice NOT-OD-11-096 NIH, AHRQ, CDC, FDA and NIOSH to Release Updated Electronic Application Forms – ADOBE-FORMS-B2. In addition, NIH will reissue R01, R03, and R21 parent announcements with the new forms on July 22 and expire the current parent R01, R03, and R21 FOAs on January 8, 2012
Funding Opportunity Announcement (FOA) Number	**PA-11-262**
Companion FOA	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.866, 93.273, 93.855, 93.856, 93.286, 93.865, 93.279, 93.242, 93.853, 93.361, 93.172
FOA Purpose	The National Institutes of Health (NIH) Investigator-Initiated Small Research Grant (R03) funding opportunity supports small research projects that can be carried out in a short period of time with limited resources. The R03 grant mechanism supports different types of

	projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology.

Key Dates

Posted Date	July 22, 2011
Open Date (Earliest Submission Date)	August 12, 2011 (Previously September 16, 2011)
Letter of Intent Due Date	Not Applicable
Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization.
AIDS Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization.
Scientific Merit Review	Standard dates apply
Advisory Council Review	Standard dates apply
Earliest Start Date(s)	Standard dates apply
Expiration Date	(Now Expiring **September 8, 2013** per issuance of PA-13-304), Originally September 8, 2014
Due Dates	Not Applicable

for E.O. 12372	

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The NIH R03 grant mechanism supports discrete, well-defined projects that realistically can be completed in two years and that require limited levels of funding. Examples of the types of projects that ICs support with the R03 mechanism include, but are not limited to, the following:

- Pilot or feasibility studies
- Secondary analysis of existing data
- Small, self-contained research projects
- Development of research methodology
- Development of new research technology

Because the research plan is restricted to 6 pages, an R03 grant application will not have the same level of detail or extensive discussion found in an R01 application. Accordingly, reviewers should evaluate the conceptual framework and general approach to the problem, placing less emphasis on methodological details and certain indicators traditionally used in evaluating the scientific merit of R01 applications including supportive preliminary data. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or from investigator-generated data. Preliminary data are not required, particularly in applications proposing pilot or feasibility studies.

Applicants are encouraged to consult the IC Contacts and Special Interests table to determine if an investigator-initiated R03 application is appropriate. **Additionally, applicants are strongly encouraged to consult with the Scientific/Research Contact at the appropriate IC about their proposed research project during the concept development stage of the application.**

Section II. Award Information

Funding Instrument	Grant
Application Types Allowed	New Resubmission Revision The OER Glossary and the SF 424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon NIH appropriations, and the submission of a sufficient number of meritorious applications.
Award Budget	The combined budget for direct costs for the two year project period may not exceed $100,000. No more than $50,000 in direct costs may be requested in any single year..
Award Project Period	The total project period may not exceed two years.

NIH grants policies as described in the NIH Grants Policy Statement will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the NIH Grants Policy Statement, **are** allowed.

Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- Central Contractor Registration (CCR) – must maintain an active registration, to be renewed at least annually
- Grants.gov
- eRA Commons

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be completed by the application due date. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an

application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

NIH will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. NIH will not accept any application that is essentially the same as one already reviewed. Resubmission applications may be submitted, according to the NIH Policy on Resubmission Applications from the SF 424 (R&R) Application Guide.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the “Apply for Grant Electronically” button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

Required and Optional Components

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed.

PHS 398 Research Plan Component

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan

Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies; GWAS) as provided in the SF424 (R&R) Application Guide.

Appendix

Do not use the appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide, with the following modifications:

- No publications or other printed material, with the exception of pre-printed questionnaires or surveys, may be included in the Appendix.

Foreign Institutions

Foreign (non-US) institutions must follow policies described in the NIH Grants Policy Statement, and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov, the online portal to find and apply for grants across all Federal agencies. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement.

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically.

Important reminders:

All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the Central Contractor Registration

(CCR). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Applications that are incomplete will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-10-115,.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

The R03 small grant supports discrete, well-defined projects that realistically can be completed in two years and that require limited levels of funding. Because the research project usually is limited, an R03 grant application may not contain extensive detail or discussion. Accordingly, reviewers should evaluate the conceptual framework and general approach to the problem. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or from investigator-generated data. Preliminary data are not required, particularly in applications proposing pilot or feasibility studies.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the

project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Human Subjects Protection and Inclusion Guidelines.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the Human Subjects Protection and Inclusion Guidelines.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of

euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Not Applicable.

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), in accordance with NIH peer review policy and procedures, using the stated review criteria. Review assignments will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to the DUNS, CCR Registration, and Transparency Act requirements as noted on the Award Conditions and Information for NIH Grants website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities. More information is provided at Award Conditions and Information for NIH Grants.

Cooperative Agreement Terms and Conditions of Award

Not Applicable.

3. Reporting

When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the NIH Grants Policy Statement.

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *NIH Grants Policy Statemen*t.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the NIH Grants Policy Statement for additional information on this reporting requirement.

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Email: GrantsInfo@nih.gov

eRA Commons Help Desk(Questions regarding eRA Commons registration, tracking application status, post submission issues)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov

Scientific/Research Contact(s)

Participating ICs and their contacts are listed at http://grants.nih.gov/grants/guide/contacts/parent_R03.html

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

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Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts*. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92.

Part I Overview Information

Department of Health and Human Services

Participating Organizations

National Institutes of Health (NIH) (http://www.nih.gov)

Components of Participating Organizations

National Cancer Institute (NCI), (http://www.nci.nih.gov/)

National Eye Institute (NEI), (http://www.nei.nih.gov/)

National Heart, Lung, and Blood Institute (NHLBI), (http://www.nhlbi.nih.gov/)

National Institute on Aging (NIA), (http://www.nia.nih.gov/)

National Institute on Alcohol Abuse and Alcoholism (NIAAA), (http://www.niaaa.nih.gov/)

National Institute of Allergy and Infectious Diseases (NIAID) (http://www.niaid.nih.gov/)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), (http://www.niams.nih.gov/)

National Institute of Biomedical Imaging and Bioengineering (NIBIB), (http://www.nibib.nih.gov/)

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), (http://www.nichd.nih.gov/)

National Institute on Deafness and Other Communication Disorders (NIDCD), (http://www.nidcd.nih.gov/)

National Institute of Dental and Craniofacial Research (NIDCR), (http://www.nidcr.nih.gov/)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), (http://www.niddk.nih.gov/)

National Institute on Drug Abuse (NIDA), (http://www.nida.nih.gov/)

National Institute of Environmental Health Sciences (NIEHS), (http://www.niehs.nih.gov)

National Institute of General Medical Sciences (NIGMS), (http://www.nigms.nih.gov)

National Institute of Mental Health (NIMH), (http://www.nimh.nih.gov/)

National Institute of Neurological Disorders and Stroke (NINDS), (http://www.ninds.nih.gov/)

National Institute of Nursing Research (NINR), (http://www.ninr.nih.gov/)

National Center for Complementary and Alternative Medicine (NCCAM), (http://www.nccam.nih.gov/)

Title: Mentored Patient-Oriented Research Career Development Award (Parent K23)

Announcement Type

This Funding Opportunity Announcement (FOA) is a reissue of PA-09-043

Update: The following updates relating to this announcement have been issued:

- April 8, 2011 – Per NOT-OD-11-063, AIDS and AIDS-related applications intended for the May 7, 2011 due date should continue to use the previously issued Parent announcements. Applications intended for June 12, 2011 and subsequent due dates must use the re-issued Parent announcements. See the Parent Announcements page for appropriate links.
- April 8, 2011 - This PA has been reissued as PA-11-194.
- January 10, 2011 - See Notice NOT-GM-11-100 This Notice is to inform potential applicants that the National Institute of General Medical Sciences (NIGMS) is increasing the amount of direct costs that may be requested in applications submitted to this PA.
- September 29, 2010 (NOT-OD-11-008) - Updated Electronic Application Forms Required for F, K, T and D Submissions with Due Dates of January 25, 2011 and Beyond. Adobe B1 forms are required for due dates on or after January 25, 2011.
- August 16, 2010 - IMPORTANT NOTE! NIH has eliminated the error correction window for due dates of January 25, 2011 and beyond. As of January 25, all corrections must be complete by the due date for an application to be considered on-time. See NOT-OD-10-123.

Program Announcement (PA) Number: PA-10-060

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (http://www.grants.gov) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.

This FOA must be read in conjunction with the application guidelines included with this announcement in Grants.gov/Apply for Grants (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process at least four (4) weeks prior to the grant submission date. See Section IV.

Catalog of Federal Domestic Assistance Number(s)

93.866, 93.271, 93.855, 93.856, 93.846, 93.286, 93.398, 93.865, 93.173, 93.121, 93.847, 93.848, 93.849, 93.279, 93.113, 93.361, 93.867, 93.233, 93.837, 93.838, 93.839, 93.281, 93.853, 93.213, 93.859

Key Dates

Release/Posted Date: December 17, 2009

Opening Date: January 12, 2010 (Earliest date an application may be submitted to Grants.gov)

NOTE: On-time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization).

Application Due Date(s): Standard dates apply, please see

http://grants1.nih.gov/grants/funding/submissionschedule.htm
AIDS Application Due Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS.
Peer Review Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Council Review Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Earliest Anticipated Start Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Additional Information To Be Available Date (URL Activation Date): Not Applicable
Expiration Date: (New Date **May 8, 2011** per issuance of PA-11-194) , Original Date: January 8, 2013

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

The overall goal of NIH-supported career development programs is to help ensure that a diverse pool of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation's biomedical, behavioral, and clinical research needs.

- **Purpose.** The purpose of the NIH Mentored Patient-Oriented Research Career Development Award (K23) is to support the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research. Clinically trained professionals or individuals with a clinical degree who are interested in further career development in biomedical research that is not patient-oriented should refer to the Mentored Clinical Scientist Career Development (Parent K08) Award. Prospective candidates are encouraged to contact the relevant NIH staff for IC-specific programmatic and budgetary information: Table of Institute and Center Contacts.
- **Mechanism of Support.** This FOA will utilize the K23 award mechanism
- **Funds Available and Anticipated Number of Awards.** Awards issued under this FOA are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.
- **Budget and Project Period.** Because the nature and scope of the proposed career award program will vary from application to application and the amounts provided by the participating ICs are not uniform, it is anticipated that the size and duration of each award will also vary.

Although the financial plans of the ICs provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. Candidates can request 3-5 years of support.

- **PHS 398 Career Development Award Supplemental Form Component Sections Length:** Items 2-5 (Candidate's Background, Career Goals and Objectives, Career Development/Training Activities During Award Period, and Training in the Responsible Conduct of Research) and Item 11 (Research Strategy) are limited to a combined total of 12 pages, including tables, graphs, figures, diagrams, and charts. See http://grants1.nih.gov/grants/funding/funding_program.htm
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.
- **Number of PDs/PIs.** Only one PD/PI may be designated on the application.
- **Number of Applications.** Candidates may only have one individual Career Development Award application pending peer review at any time.
- **Resubmissions.** Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement). See new NIH policy on resubmission (amended) applications (NOT-OD-09-003, NOT-OD-09-016).
- **Renewals.** Awards are not renewable and are not transferable from one PD/PI to another.
- **Application Materials.** See Section IV.1 for application materials.
- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:
    - SF424 (R&R) Application and Electronic Submission Information: http://grants.nih.gov/grants/funding/424/index.htm
    - General information on Electronic Submission of Grant Applications: http://era.nih.gov/ElectronicReceipt/
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (301) 451-5936

Table of Contents

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

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1. Research Career Objectives

The overall goal of NIH-supported career development programs is to help ensure that a diverse pool of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation's biomedical, behavioral, and clinical research needs. The objective of the NIH Mentored Patient-Oriented Research Career Development Award (K23) program is to ensure a future cadre of well-trained scientists working in POR areas who will become competitive for NIH research project (R01) grant support. The specific objectives of the Mentored Patient-Oriented Research Career Development Award are to:

- Encourage research-oriented clinicians to develop independent research skills and gain experience in advanced methods and experimental approaches needed to become an independent investigator conducting patient-oriented research.
- Increase the pool of clinical researchers who can conduct patient-oriented studies, capitalizing on the discoveries of biomedical research and translating them to clinical settings.
- Support the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research.

For the purposes of this award, **Patient-Oriented Research** is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects. This area of research includes: 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials, and; 4) the development of new technologies. Studies falling under Exemption 4 for human subjects research are not included in this definition. See also:

http://www.oenb.at/de/img/executive_summary--nih_directors_panel_on_clinical_research_report_12_97_tcm14-48582.pdf.

Note: NIH Institutes and Centers have unique scientific purviews and different program goals and initiatives. Therefore, candidates are strongly encouraged to contact appropriate NIH staff for IC-specific programmatic and budgetary information: Table of Institute and Center Contacts.

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Section II. Award Information

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1. Mechanism of Support

This FOA will use the NIH Mentored Patient-Oriented Research Career Development (K23) award mechanism. The Project Director/Principal Investigator (PD/PI; also referred to as the Candidate) and his/her mentor (if applicable) will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses “Just-in-Time” information concepts (see SF424 (R&R) Application Guide). It also uses the non-modular budget format.

The candidate should follow the instructions for budget information described in Section IV (6.F) as well as in PHS 398 Career Development Award Supplemental form Section 7.4.6 of the R&R 424 instructions, and budget justification information.

The K23 program must be tailored to meet the individual needs of the candidate. Candidates may request 3 to 5 years of support. The actual duration of the award will depend upon the number of years of prior research experience, the demonstrated need for additional mentored experience to achieve research independence, and the policy of the awarding Institute or Center (IC). Awards are not renewable and are not transferable from one PD/PI to another.

2. Funds Available

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds.

NIH grants policies as described in the Table of Institute and Center Contacts). The total salary requested must be based on a full-time, 12-month staff appointment. The K23 requires the candidate to devote a minimum of 9

person-months (75% of full-time professional effort) to conducting health-related research. The remaining effort may be devoted to clinical, teaching, or other research pursuits and activities consistent with the objectives of the awarded grant. For information regarding NIH policy on determining full-time professional effort for career awards, see NOT-OD-04-056.

The salary must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure. Confirmation of salary may be required prior to the issuance of an award. Fringe benefits, based on the sponsoring institution's rate and the percent of effort, are provided in addition to the salary.

The sponsoring institution may supplement the NIH salary contribution up to a level that is consistent with the institution's salary scale. However, supplementation may not be from Federal funds unless specifically authorized by the Federal program from which such funds are derived. In no case may PHS funds be used for salary supplementation. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the K01 award. Under expanded authorities, however, institutions may re-budget funds within the total costs awarded to cover salaries consistent with the institution's salary scale. The total salary, however, may not exceed the legislatively mandated salary cap. See: http://grants.nih.gov/grants/policy/salcap_summary.htm.

K23 award recipients are encouraged to obtain funding from NIH or other Federal sources either as a named PD/PI on a competing research grant award or cooperative agreement or as sub-project director on a competing multi-project award (see NOT-OD-08-065). Within the last two years of a K23 award, the effort required on the K23 award may be reduced to no less than 6 person-months (50% full-time professional effort) at the grantee organization and replaced by effort from the research award so that the total level of research commitment remains at 9 person-months (75% full-time professional effort) or more for the duration of the K23 award. To be eligible for salary support from peer-reviewed research awards from any Federal agency:

- The K23 award recipient must be identified as the PD/PI (or one of the named PD/PIs, if following the multiple-PD/PI model) at the time of review on a competing NIH research grant application (R01, R03, R15, R21, R34, or equivalent application from another Federal agency) or a sub-project director on a competing multi-component research or center grant or cooperative agreement application (P01, P50, U01, etc. or an equivalent application from another Federal agency).
- The K23 award must be active when the competing research grant application is submitted.
- The K23 award must be in its final two years before the reduction in effort to 6 person-months (50% full-time professional effort) is permitted.

Research Development Support: The participating NIH Institutes and Centers will provide research development support for the K23 award recipient (see Table of Institute and Center Contacts). These costs may be used for the following expenses: (a) tuition and fees related to career development; (b) research expenses, such as supplies, equipment and technical personnel; c) travel to research meetings or training; and (d) statistical services including personnel and computer time.

Ancillary Personnel Support: Salary for secretarial and administrative assistance, etc., is not allowed.

Indirect Costs: These costs also known as Facilities and Administrative (F&A) costs, will be reimbursed at eight percent (8%) of modified total direct costs.

Section III. Eligibility Information

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1. Eligible Applicants

1.A. Eligible Institutions

The following organizations/institutions are eligible to apply:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Small Businesses
- For-Profit Organizations (Other than Small Businesses)
- State Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribally Designated Organizations
- County Governments
- City or Township Governments
- Special District Governments
- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities

- U.S. Territory or Possession
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Regional Organizations
- Other(s): Faith-based or Community-based Organizations.

Foreign institutions are not eligible to apply.

1.B. Eligible Individuals

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

Project Director/Principal Investigator (PD/PI): Also referred to as the Candidate, individuals with the skills, knowledge, and resources necessary to carry out the proposed research and career development activities are invited to work with their mentor and sponsoring institution to develop an application for support. Individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds are always encouraged to apply for NIH support.

Citizenship and Residency: Only U.S. citizens or non-citizen nationals, or individuals lawfully admitted for permanent residence who have a currently valid Permanent Resident Card (USCIS Form I-551), or some other verification of legal admission as a permanent resident prior to the time of award, are eligible for this award. Non-citizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S. They are usually born in lands that are not states but are under U.S. sovereignty, jurisdiction, or administration. Individuals on temporary or student visas are not eligible.

Degree and Research: Candidates for this award must have a health-professional doctoral degree. Such degrees include but are not limited to the M.D., D.O., D.D.S., D.M.D., O.D., D.C., Pharm.D., N.D. (Doctor of Naturopathy), as well as a doctoral degree in nursing research or practice. Candidates with Ph.D. degrees are eligible for this award if the degree is in a clinical field and they usually perform clinical duties. This may include clinical psychologists, clinical geneticists, social workers, speech and language pathologists, audiologists, and rehabilitationists. Individuals holding the Ph.D. in a non-clinical discipline but who are certified to perform clinical duties should contact the appropriate Institute concerning their eligibility for a K23 award. Candidates also must have completed their clinical training, including specialty and, if applicable, subspecialty training prior to receiving an award. However, candidates may submit an application prior to the completion of clinical training.

Level of Effort: Candidates must be able to commit a minimum of 9 person-months (75% of full-time professional effort) conducting research career development activities associated with this award. The remaining

3 months (25% effort) can be divided among other research, clinical, and teaching activities only if these activities are consistent with the goals of an NIH K23 Award, i.e., the candidate's development into an independent investigator. For information regarding NIH policy on determining full-time professional effort for career awards, see NOT-OD-04-056.

At the time of award, the candidate must have a "full-time" appointment at the academic institution that is the applicant institution. Candidates who have VA appointments may not consider part of the VA effort toward satisfying the "full time" requirement at the applicant institution. Candidates with VA appointments should contact the staff person in the relevant Institute or Center prior to preparing an application to discuss their eligibility.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current *NIH Grants Policy Statement.*

3. Other-Special Eligibility Criteria

Number of Applications. Applicants may only have one individual Career Development Award application pending peer review at any time.

A candidate for an NIH K23 award may not simultaneously submit or have an application pending for any other NIH career award (e.g., K01, K07, K08, K22, K23, K25), a research project grant (R01), or any PHS award that duplicates any of the provisions of the K23 award. Ineligible individuals include current and former principal investigators on NIH research project grants, comparable individual career development awards (e.g., K01, K07, K08, K23, K25) equivalent non-PHS peer-reviewed research grants that are over $100,000 direct costs per year, or project leaders on sub-projects of program project (P01) or center (P50) grants. Former principal investigators of NIH Small Grants (R03) or Exploratory/Developmental Grants (R21) remain eligible.

Current and former recipients of Clinical Associate Physicians Award (CAP) support may apply for the K23 provided they've had no more than 3 years of CAP support by the time of the K23 award. The combined total of CAP plus K23 support must not exceed 6 years.

K23 recipients are encouraged to apply for independent research grant support during the latter period of this award. K23 award recipients that obtain independent support during the K23 award period may hold concurrent research support, and under certain circumstances (see Allowable Costs above) salary support from their career award and a competing NIH research project grant when recognized as a Principal Investigator or subproject Director of the research project grant, see NOT-OD-08-065.

Resubmissions. Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement). Beginning with applications

intended for the January 25, 2009 official submission due date, all original new applications (i.e., never submitted) and competing renewal applications are permitted only a single amendment (A1). See new NIH policy on resubmission (amended) applications (NOT-OD-09-003, NOT-OD-09-016). Original new and competing renewal applications that were submitted prior to January 25, 2009 are permitted two amendments (A1 and A2). For these "grandfathered" applications, NIH expects that any A2 will be submitted no later than January 7, 2011, and NIH will not accept A2 applications after that date.

Renewals. Awards are not renewable and are not transferable from one PD/PI to another.

3. A. Special Requirements

Mentor(s): The candidate must name a primary sponsor/mentor, who together with the candidate is responsible for the planning, direction, and execution of the program. The mentor should be recognized as an accomplished investigator in the proposed program and have a track record of success in training similar investigators. The mentor should have sufficient independent support to cover the costs of the proposed project in excess of the allowable costs of this award. Candidates may also nominate co-mentors as appropriate to the goals of the program. Where feasible, women, individuals from diverse racial and ethnic groups, and individuals with disabilities should be involved as mentors to serve as role models. Appropriate mentors include, but are not limited to, NIH-supported investigators involved in POR.

Institutional Environment: The applicant institution must have a strong, well-established record of career development activities and faculty qualified in biomedical, behavioral, or clinical research to serve as mentors. The institution must demonstrate a commitment to the development of the candidate as a productive investigator and be willing to allow the protected time needed by the candidate. The candidate, mentor, and institution must describe a career development program that will maximize the use of this environment, including available facilities and resources.

Section IV. Application and Submission Information

To download a SF424 (R&R) Application Package and SF424 (R&R) Application Guide for completing the SF424 (R&R) forms for this FOA, use the "Apply for Grant Electronically" button in this FOA or link to http://www.grants.gov/Apply/ and follow the directions provided on that Web site.

Registration:

Appropriate registrations with Grants.gov and eRA Commons must be completed on or before the due date in order to successfully submit an application**. Several of the steps of the registration process could take four**

weeks or more. Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered with both Grants.gov and the Commons. All registrations must be complete by the submission deadline for the application to be considered "on-time" (see 3.C.1 for more information about on-time submission).

A one-time registration is required for institutions/organizations at both:

- Grants.gov (http://www.grants.gov/applicants/get_registered.jsp) and
- eRA Commons (http://era.nih.gov/ElectronicReceipt/preparing.htm)

The PD/PI should work with their institutions/organizations to make sure they are registered in the NIH eRA Commons.

Several additional separate actions are required before an applicant can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov/Get Registered

- Your organization will need to obtain a Data Universal Number System (DUNS) number and register with the Central Contractor Registration (CCR) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to:
  Grants.gov Customer Support
  Contact Center Phone: 800-518-4726
  Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time
  Email support@grants.gov

2) Organizational/Institutional Registration in the eRA Commons

- To find out if an organization is already Commons-registered, see the "List of Grantee Organizations Registered in NIH eRA Commons."
- Direct questions regarding the Commons registration to:
  eRA Commons Help Desk
  Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939
Business hours M-F 7:00 a.m. – 8:00 p.m. Eastern Time
Email commons@od.nih.gov

3) Project Director/Principal Investigator (PD/PI) Registration in the NIH eRA Commons: Refer to the *NIH eRA Commons System (COM) Users Guide*.

- The individual designated as PD/PI on the application must be registered also in the NIH eRA Commons.
- The PD/PI must hold a PD/PI account in the Commons. Applicants should not share a Commons account for both an Authorized Organization Representative/Signing Official (AOR/SO) role and a PD/PI role; however, if they have both a PD/PI role and an Internet Assisted Review (IAR) role, both roles should exist under one Commons account.
- This registration/affiliation must be done by the AOR/SO or his/her designee who is already registered in the Commons.

Both the PD/PI and AOR/SO need separate accounts in the NIH eRA Commons since both are authorized to view the application image.

Note: The registration process is not sequential. Applicants should begin the registration processes for both Grants.gov and eRA Commons as soon as their organization has obtained a DUNS number. Only one DUNS number is required and the same DUNS number must be referenced when completing Grants.gov registration, eRA Commons registration and the SF424 (R&R) forms.

1. Request Application Information

Applicants must download the SF424 (R&R) application forms and the SF424 (R&R) Application Guide for this FOA through Grants.gov/Apply.

Note: Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA), although some of the "Attachment" files may be useable for more than one FOA.

For further assistance, contact GrantsInfo -- Telephone 301-435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY: (301) 451-5936

2. Content and Form of Application Submission

Prepare all applications using the SF424 (R&R) application forms for this FOA through Grants.gov/Apply and in accordance with the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/index.htm).

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to NIH. Some fields within the SF424 (R&R) application components, although not marked as mandatory, are required by NIH (*e.g., the "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component must contain the PD/PI's assigned eRA Commons User ID*). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see "Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications."

The SF424 (R&R) application has several components. Some components are required, others are optional. The forms package associated with this FOA in Grants.gov/APPLY includes all applicable components, required and optional. A completed application in response to this FOA includes the data in the following components:

Required Components:

SF424 (R&R) (Cover component)
Research & Related Project/Performance Site Locations
Research & Related Other Project Information
Research & Related Senior/Key Person
PHS398 Cover Letter
PHS398 Cover Page Supplement
PHS398 Career Development Award Supplemental Form
PHS398 Checklist
SF424 (R&R) Detailed Budget

3. Submission Dates and Times

See Section IV.3.A. for details.

3.A. Submission, Review, and Anticipated Start Dates

Opening Date: January 12, 2010 (Earliest date an application may be submitted to Grants.gov)
Application Due Date(s): Standard dates apply, please see
http://grants.nih.gov/grants/funding/submissionschedule.htm
AIDS Application Due Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS
Peer Review Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Council Review Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward

Earliest Anticipated Start Date(s): Standard dates apply, please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward

3.A.1. Letter of Intent

A letter of intent is not required for the funding opportunity.

3.B. Submitting an Application Electronically to the NIH

To submit an application in response to this FOA, applicants should access this FOA via http://www.grants.gov/applicants/apply_for_grants.jsp and follow Steps 1-4. Note: Applications must only be submitted electronically**. PAPER APPLICATIONS WILL NOT BE ACCEPTED.** All attachments must be provided to NIH in PDF format, filenames must be included with no spaces or special characters, and a .pdf extension must be used.

3.C. Application Processing

3.C.1 Submitting On-Time

Applications **may** be submitted on or after the opening date and **must** be successfully received by Grants.gov no later than **5:00 p.m. local time** (of the applicant institution/organization) on the application due date(s). (See Section IV.3.A. for all dates.) If an application is not submitted by the due date(s) and time, the application may be delayed in the review process or not reviewed. All applications must meet the following criteria to be considered “on-time”:

- All registrations must be complete prior to the submission deadline
- The application must receive a Grants.gov tracking number and timestamp (or eRA help desk ticket confirming a system issue preventing submission) by 5:00 p.m. local time on the submission deadline date.
- Any system identified errors/warnings must be corrected and the submission process completed within the “error correction window.”

Please visit http://era.nih.gov/electronicReceipt/app_help.htm for detailed information on what to do if Grants.gov or eRA system issues threaten your ability to submit on time.

Submission to Grants.gov is not the last step – applicants must follow their application through to the eRA Commons to check for errors and warnings and view their assembled application!

3.C.2 Two Day Window to Correct eRA Identified Errors/Warnings

IMPORTANT NOTE! NIH has eliminated the error correction window for due dates of January 25, 2011 and beyond. As of January 25, all corrections must be complete by the due date for an application to be considered on-time. See NOT-OD-10-123.

Once an application package has been successfully submitted through Grants.gov, NIH provides applicants a two day *error correction window* to correct any eRA identified errors or warnings before a final assembled application is created in the eRA Commons. The standard error correction window is two (2) business days, beginning the day after the submission deadline and excluding weekends and standard federal holidays. All errors must be corrected to successfully complete the submission process. Warnings will not prevent the application from completing the submission process.

Please note that the following caveats apply:

- Initial application submission must be "on-time."
- The AOR/institutions is expected to enforce that application changes made within the error correction window are restricted to those necessary to address system-identified errors/warnings. NIH may reject any application that includes additional changes.
- Proof of "on-time" submission (e.g., Grants.gov timestamp and tracking number) and description of all changes made within the window must be documented in the PHS 398 Cover Letter component of the application.

3.C.3 Viewing an Application in the eRA Commons

Once any eRA identified errors have been addressed and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two weekdays (Monday – Friday, excluding Federal holidays) to view the assembled application before it automatically moves forward to NIH for further processing.

- If everything is acceptable, no further action is necessary. The application will automatically move forward to the Division of Receipt and Referral in the Center for Scientific Review for processing after two weekdays, excluding Federal holidays.
- Prior to the submission deadline, the AOR/SO can "Reject" the assembled application and submit a changed/corrected application within the two-day viewing window. This option should be used if it is determined that some part of the application was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to "Reject" the application and submit a Changed/Corrected application. In these cases, please contact the eRA Help Desk to ensure that the issues are addressed and corrected. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12 of the SF 424 (R&R) application guide, including the requirement for cover letters on late applications. The "Reject" feature should also

be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two weekdays if no action is taken. Some warnings may need to be addressed later in the process.

- If the two-day window falls after the submission deadline, the AOR/SO will have the option to "Reject" the application if, due to an eRA Commons or Grants.gov system issue, the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn't transfer correctly during the submission process). The AOR/SO should first contact the eRA Commons Helpdesk to confirm the system error, document the issue, and determine the best course of action. NIH will not penalize the applicant for an eRA Commons or Grants.gov system issue.
- If the AOR/SO chooses to "Reject" the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted, but it will be subject to the NIH late policy guidelines and may not be accepted. The reason for this delay should be explained in the cover letter attachment.
- Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two weekdays.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Incomplete applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the Commons. The submitting AOR/SO receives the Grants.gov acknowledgments. The AOR/SO and the PI receive Commons acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

Note: Since email can be unreliable, it is the responsibility of the applicant to check periodically on their application status in the Commons.

The NIH will not accept any application in response to this FOA that is essentially the same as one currently pending initial merit review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. However, the NIH will accept a resubmission application, but such application must include an Introduction addressing the critique from the previous review.

4. Intergovernmental Review

This initiative is not subject to *intergovernmental review*.

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Citizenship: Candidates must meet the citizenship requirements as described in the Eligibility section of this announcement (see Section III) at the time of award.

Concurrent Awards: Candidates must be aware of the NIH policies associated with other federally sponsored support (see: NOT-OD-08-065).

Salary Support: The salary requested for the candidate must be consistent with both the established salary structure for full-time staff appointments and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the applicable department.

NIH policy allows NIH mentored career development award recipients in the final two years of their award to receive salary support from both their K award and a research grant from any Federal agency (see NOT-OD-08-065). The K-award recipient must be a named PD/PI of a competing research project grant (R01, R03, R15, R21, R34, etc.), or be the sub-project director on a competing multi-component research or center grant or cooperative agreement (P01, P50, U01, etc.). See the Notice for full details.

Research Development Support: The research development support costs allowed for this program must be justified and be consistent with the stage of development of the candidate and the proportion of time to be spent in research or career development activities. Salary for ancillary personnel support, such as mentors, secretarial and administrative assistants is not allowed.

Pre-Award Costs: Pre-award costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period if such costs: 1) are necessary to conduct the project, and 2) would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not

impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See NIH Grants Policy Statement NIH Grants Policy Statement.

6. Other Submission Requirements

PD/PI Credential (e.g., Agency Login): The NIH requires the PD/PI to fill in his/her Commons User ID in the "PROFILE – Project Director/Principal Investigator" section, "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component.

Organizational DUNS: The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see "Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications."

Cover Letter: The PHS398 cover letter must include the list of referees (including name, department affiliation, and institution.

PHS 398 Career Development Award Supplemental Form Component Sections

All application instructions outlined in the SF424 (R&R) Application Guide (See Supplementary Instructions for Research Career Awards, Part I.7.5) are to be followed, incorporating "Just-in-Time" information concepts, and with the following additional requirements:

- Introduction (required for a resubmission or revision application) is limited to 1 page.
- Specific Aims is limited to 1 page.
- Items 2-5 (Candidate's Background, Career Goals and Objectives, Career Development/Training Activities During Award Period, and Training in the Responsible Conduct of Research) and Item 11 (Research Strategy) are limited to a combined total of 12 pages, including tables, graphs, figures, diagrams, and charts.
- While each section of the Candidate Information and Research Strategy components needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Candidate Information component and the Research Strategy component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to better monitor formatting requirements such as page limits.

Candidate Information and Career Development Plan

Candidate's Background:

- Describe the candidate's commitment to an academic career in Patient-Oriented Research (POR. Include a description of all of the candidate's professional responsibilities in the grantee institution and elsewhere and show their relation to the proposed activities on the career award.
- Present evidence of the candidate's ability to interact and collaborate with other scientists.
- Describe prior training and how it relates to the objectives and long-term career plans of the candidate.
- Describe the candidate's research efforts to this point in his/her research career, including any publications, prior research interests and experience.
- Provide evidence of the candidate's potential to develop into an independent investigator.
- Include a statement that the candidate will commit at least 9 person-months (75% of full-time professional effort) to the POR program and related career development activities. The mentor or department chair must agree and provide a statement in the application documenting that this percent of the candidate’s time will be protected.

Career Goals and Objectives:

- Describe a systematic plan: (1) that shows a logical progression from prior research and training experiences to the training and research experiences that will occur during the career award period and then to independent investigator status; (2) that justifies the need for further career development to become an independent investigator; and (3) that utilizes the relevant research and educational resources of the institution.

Career Development/Training Activities:

- The candidate and the mentor are jointly responsible for the preparation of the career development plan. A timeline is often helpful. The sponsor/mentor may form an advisory committee to assist with the development of the program of study or to monitor the candidate's progress through the career development program.
- The didactic (if any) and the research aspects of the plan must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the candidate's career goals. The candidate must demonstrate they have received training or will participate in courses such as: data management, epidemiology, study design(including statistics), hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects.
- Describe the professional responsibilities/activities including other research projects) beyond the minimum required 75% effort commitment to the K23 award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator conducting patient-oriented research.

Training in the Responsible Conduct of Research:

- Applications must include a plan to obtain instruction in the responsible conduct of research.
- This section should document prior instruction in responsible conduct of research during the applicant's current career stage (including the date of last occurrence) and propose plans to receive instruction in responsible conduct of research.
- Such plans must address five instructional components, format, subject matter, faculty participation, duration of instruction, and frequency of instruction, as outlined and explained in **NOT-OD-10-019**.
- The plan may include career stage-appropriate, individualized instruction or independent scholarly activities that will enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research.
- The role of the sponsor/mentor in responsible conduct of research instruction must be described.
- Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process.
- The background, rationale and more detail about instruction in the responsible conduct of research can be found in **NOT-OD-10-019**.

Research Plan

The research plan should follow instructions outlined in PHS 398 Career Development Award Supplemental form, including sections on Specific Aims and Research Strategy. The candidate should consult with the mentor(s) regarding the development of this section.

- A sound research project that is consistent with the candidate's level of research development and objectives of his/her career development plan must be provided. The research description should demonstrate not only the quality of the candidate's research thus far but also the novelty, significance, creativity and approach, as well as the ability of the candidate to carry out the research.
- While the focus of the K23 award is on POR, complementary laboratory research directly related to patient-oriented research may be proposed in the application, thereby providing an opportunity for a career development experience in translational research.
- The application must also describe the relationship between the mentor's research and the candidate's proposed research plan.
- If more than one mentor is proposed, the respective areas of expertise and responsibility should be described.
- Data and Safety Monitoring (when applicable): Individual NIH institutes may have specific requirements for data and safety monitoring of clinical trials. Candidates proposing to conduct

clinical trials should consult with relevant IC staff. Plans for data and safety monitoring must be included in research plans involving Phase I or Phase II clinical trials (see Federal Citations in Section VIII): Generally, this requirement may be satisfied in the submitted application by providing documentation that the sponsoring institution has an approved plan in place and providing a brief description of the key elements of the plan.

Statements of Support

Statement by Mentor, Co-Mentors, Consultants, Contributors (All statements/letters should be appended to each other and uploaded as a single pdf document):

- The candidate must name a primary mentor who, together with the candidate, is responsible for the planning, directing, monitoring, and executing the program. The candidate may also nominate co-mentors as appropriate to the goals of the program.
- The mentor should be recognized as an accomplished investigator in the proposed research area and have a track record of success in training and placing independent investigators.
- The mentor should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award.
- Where feasible, women, individuals from diverse racial and ethnic groups, and individuals with disabilities should be involved as mentors to serve as role models.
- The application must include a statement from the mentor providing: 1) information on his/her research qualifications and previous experience as a research supervisor; 2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period; 3) a plan for career progression for the candidate to move from the mentored stage of his/her career to the independent research investigator status during the project period of the award including what aspects of the proposed research the candidate will be able to take into their independent position; and 4) a plan for monitoring the candidate's research, publications, and progression towards independence.
- Similar information must be provided by any co-mentor. If more than one co-mentor is proposed, the respective areas of expertise and responsibility of each should be described. Co-mentors should clearly describe how they will coordinate the mentoring of the candidate. If any of the co-mentors are not located at the sponsoring institution, a statement should be provided describing the mechanism(s) and frequency of communication with the candidate, including the frequency of personal meetings.
- Consultant(s)/Collaborator(s): Signed statements must be provided by each consultant/collaborator confirming their participation in the project and describing their specific roles. Collaborators and consultants generally do not need to provide their biographical sketches. However, information should be provided clearly documenting the appropriate expertise in the proposed areas of consulting/collaboration. Collaborators/consultants are

generally not directly involved in the development of the career of the candidate as an independent investigator.

- The mentor must agree to provide annual evaluations of the candidate's progress as required in the annual progress report, PHS 2590 (see Section VI.3. Reporting).

Environment and Institutional Commitment to the Candidate

Description of Institutional Environment:

- The sponsoring institution must document a strong, well-established research and career development program related to the candidate's area of interest, including a high-quality research environment with key faculty members and other investigators capable of productive collaboration with the candidate.
- Describe how the institutional research environment is particularly suited for the development of the candidate's research career and the pursuit of the proposed research plan.
- Describe the resources and facilities that will be available to the candidate, including any resources that are within a General Clinical Research Center (GCRC) or Clinical and Translational Science Award (CTSA).

Institutional Commitment to Candidate's Research Career Development:

- The sponsoring institution must provide a statement of commitment to the candidate's development into a productive, independent investigator and to meeting the requirements of this award. It should be clear that the institutional commitment to the candidate is not contingent upon receipt of this career award.
- Provide assurances that the candidate will be able to devote a minimum of 9 person-months (75% of full-time professional effort) to the development of their research program. The remaining effort should be devoted to activities related to the development of the candidate's career as an independent clinician scientist, e.g. clinic responsibilities, teaching and administration, and/or additional research activities.
- Provide the candidate with appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations) to carry out the proposed research plan.
- Provide appropriate time and support for any proposed mentor(s) and/or other staff consistent with the career development plan.
- Candidates who will be using the resources within a General Clinical Research Center (GCRC) or Clinical and Translational Science Award (CTSA) during the course of the award are requested to include a letter of agreement from either the GCRC or CTSA program director or the principal investigator as part of the application.

Budget for the Entire Proposed Period of Support

Allowable costs for this career award program are not uniform throughout the participating Institutes and Centers; therefore the salary amounts as well as the research development costs vary. See: Table of Institute and Center Contacts.

Budget Component (Section 4.7): Use the SF424 (R&R) Detailed Budget component and review the instructions found in Part I.4.7(R&R Budget Component) of the Application Guide. However for "K" applications only limited budget information is required; therefore, candidates will also need to follow the special instructions in Part I.7.4 of the SF 424 (R&R) [Supplemental Instructions for Career Development Awards], noting the special instructions that modify Section 4.7. In budget section A (Senior/Key Persons) include base salary, person months and requested salary and fringe benefit information for only the candidate. Base salary, and requested salary and fringe benefits should reflect actual levels. Any adjustments based on IC policy limits will be made at the time of the award. Sections B-E should be left blank. If a dollar amount is required, enter 0 (zero) in the appropriate box. The total Research Development Support amount requested for each year will be entered in Section F, Materials and Supplies. In Section H enter Modified Total Direct Costs under "Indirect Cost Type." The Indirect Cost rate is 8% of modified total direct cost. The Indirect Cost amount should be entered under "Funds Requested." Totals for Sections F, G, and H will be calculated automatically for each year as well as for the Cumulative Budget. Within the direct cost limitation for research development support, provide a detailed description with justification for all equipment, supplies and personnel that will be used to help achieve the career development and research objectives of this award.

Letters of Reference

Electronic submission of reference letters is a separate process from submitting an application electronically. Reference letters are submitted directly through the eRA Commons and do not use Grants.gov. Therefore, candidates must follow the Supplemental Instructions in the SF424 R&R Application Guide for Research Career Awards (Instructions, Part 7.3) (see http://grants.nih.gov/grants/funding/424/index.htm).

Letters of reference are an important component of the application for the mentored career award. Candidates for this career award must arrange to have **at least three (but no more than five)** letters of reference submitted on their behalf to the NIH eRA Commons Web site at https://public.era.nih.gov/commons/public/reference/submitReferenceLetter.do?mode=new. The letters should be from well-established scientists (referees) addressing the qualities of the candidate as well as their potential for becoming an independent investigator. These letters should be from individuals not directly involved in the application, but who are familiar with the candidate's qualifications, training, and interests, including advisory committee members (if applicable).

The mentor/co-mentor(s) may also submit letters of reference, but these letters will be considered independently of the three required reference letters. Resubmission applications must include new letters of reference.

Applications that are missing the required letters of reference may be delayed in the review process or not accepted.

Appendix Materials

Applicants **must** follow the specific instructions on Appendix materials as described in the SF424 (R&R) Application Guide (See http://grants.nih.gov/grants/funding/424/index.htm).

Do not use the Appendix to circumvent the page limitations. An application that does not comply with the required page limitations may be delayed in the review process.

Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. If the final data/resources are not amenable to sharing, this must be explained in the Resource Sharing section of the application (see http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm).

(a) *Data Sharing Plan*: Not Applicable

(b) *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms and related resources, or state appropriate reasons why such sharing is restricted or not possible. See Sharing Model Organisms Policy, and NIH Guide NOT-OD-04-042.

(c) *Genome-Wide Association Studies (GWAS):* Regardless of the amount requested, applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. A genome-wide association study is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (e.g., blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (go to NOT-OD-07-088, and http://grants.nih.gov/grants/gwas/.)

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Review Process

Applications submitted for this funding opportunity will be assigned on the basis of established PHS referral guidelines to the ICs for funding consideration.

Applications that are complete will be evaluated for scientific and technical merit by (an) appropriate scientific review group(s) in accordance with NIH peer review procedures (http://grants1.nih.gov/grants/peer/) using the review criteria stated below.

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned an impact/priority score;
- Receive a written critique; and
- Receive a second level of review by appropriate national advisory council or board.

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. The overall goal of NIH-supported career development programs is to help ensure that diverse pools of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation's biomedical, behavioral, and clinical research needs. The scientific review group will address and consider the review criteria in assigning the application's overall score, weighting them as appropriate for each application.

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the candidate to maintain a strong research program, in consideration of the following five scored review criteria, and additional review criteria. An application does not need to be strong in all categories to have a major impact.

Reviewers should recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator.

Scored Review Criteria. Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each.

Candidate.

- Does the candidate have the potential to develop as an independent and productive researcher focusing on patient-oriented research?
- Is the candidate's academic, clinical, and (if relevant) research record of high quality?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator focusing on patient-oriented research?
- Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high potential for becoming an independent investigator?

Career Development Plan.

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence?
- Is the candidate's prior training and research experience appropriate for this award?
- Are the goals and scope of the plan when considered in the context of prior training/research experience and the stated training and research objectives, appropriate?
- Are the content and duration of the proposed didactic research activities during the proposed award period clearly stated and appropriate?
- Are there adequate plans for evaluating the candidate's research and career development progress?

Research Plan.

- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Is the research plan relevant to the candidate's research career objectives focusing on patient-oriented research?
- Is the plan for developing/enhancing the candidate's research skills appropriate and adequate?
- If applicable, are there adequate plans for data and safety monitoring of clinical trials?

Mentor(s), Consultant(s), Collaborator(s).

- Are the mentor's research qualifications in the area of the proposed patient-oriented research appropriate?

- Do the mentor(s) adequately address the above review criteria including the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?
- Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of previous research productivity and peer-reviewed support focusing on patient-oriented research?
- Is there active/pending support for the proposed research project appropriate and adequate?
- Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence??

Environment and Institutional Commitment to the Candidate.

- Is there clear commitment of the sponsoring institution to ensure that a minimum of 75% of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program?

Additional Review Criteria

As applicable for the project proposed, reviewers will consider **the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items**.

Protections for Human Subjects. For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

Inclusion of Women, Minorities, and Children. When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Vertebrate Animals. The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

Biohazards. Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission Applications. When reviewing a Resubmission application (formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal Applications. Not Applicable.

Revision Applications. This criterion is generally not applicable to K awards. Under rare circumstances, when reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

***Training in the responsible conduct of research*:** Reviewers will evaluate plans for instruction in responsible conduct of research as well as the past record of instruction in responsible conduct of research, where applicable. Reviewers will specifically address the five Instructional Components (Format, Subject Matter, and

Frequency of instruction as detailed in NOT-OD-10-019. The review of this consideration will be guided by the principles set forth in NOT-OD-10-019. Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE.

Select Agents Research. Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm); 2) Sharing Model Organisms (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html); and 3) Genome Wide Association Studies (GWAS) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html).

Budget and Period of Support. Reviewers will consider whether the budget and the requested period of career development support are fully justified and reasonable in relation to the proposed research.

Selection Process

Applications submitted in response to this funding opportunity will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed research career development program as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

Not Applicable

Section VI. Award Administration Information

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1. Award Notices

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the NIH eRA Commons.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the *NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General*.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Section IV.5., “Funding Restrictions.”

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities.

The following related administrative policies apply to NIH Research Career Award (“K”) programs:

A. Evaluation: In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of this program. Accordingly, recipients are hereby notified that they may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

B. Other Income: Awardees may retain royalties and fees for activities such as scholarly writing, service on advisory groups, honoraria from other institutions for lectures or seminars, fees resulting from clinical practice, professional consultation or other comparable activities, provided these activities remain incidental, are not required by the research and research-related activities of this award, and provided that the retention of such pay is consistent with the policies and practices of the grantee institution.

All other income and fees, not included in the preceding paragraph as retainable, may not be retained by the career award recipient. Such fees must be assigned to the grantee institution for disposition by any of the following methods:

- The funds may be expended by the grantee institution in accordance with the NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefit payments must be within the established policies of the grantee institution.
- The funds may be used for health-related research purposes.
- The funds may be paid to miscellaneous receipts of the U.S. Treasury. Checks should be made payable to the Department of Health and Human Services, NIH and forwarded to the Director, Office of Financial Management, NIH, Bethesda, Maryland 20892. Checks must identify the relevant award account and reason for the payment.

Usually, funds budgeted in an NIH supported research grant for the salaries or fringe benefits of individuals, but freed as a result of a career award, may not be rebudgeted. The awarding component will give consideration to approval for the use of released funds only under unusual circumstances. Any proposed retention of funds released as a result of a career award must receive prior written approval of the NIH awarding component.

C. Leave Policies: Leave to another institution, including a foreign laboratory, may be permitted if the proposed experience is directly related to the purpose of the award. Only local institutional approval is required if such leave does not exceed 3 months. For longer periods, prior written approval of the NIH funding component is required. Details on the process for submission of prior approval requests can be founds in the NIHGPS, Requests for Prior Approval, at http://grants.nih.gov/archive/grants/policy/nihgps_2003/index.htm#_Toc54600130.

A copy of a letter or other evidence from the institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made. Support from the career award will continue during such leave.

Leave without award support may not exceed 12 months. Such leave requires the prior written approval of the NIH component Institute or Center and will be granted only in unusual situations.

Support from other sources is permissible during the period of leave without award support. Such leave does not reduce the total number of months of program support for which an individual is eligible.

D. Percent Effort Policies: Under certain circumstances, an awardee may submit a written request to the awarding component requesting a reduction in professional effort below 75 percent (equivalent to 9 person months). Such requests will be considered on a case-by-case basis during the award period. In no case will it be permissible to work at less than 50 percent effort (equivalent to 6 person months). The nature of the circumstances requiring a change in the appointment status or percent effort might include personal or family situations such as parental leave, child care, elder care, medical conditions, or a disability. Permission to reduce the level of effort will not be approved to accommodate job opportunities, clinical practice, or clinical training. In

each situation, the grantee institution must submit documentation supporting the need for reduced effort along with assurance of a continuing commitment to the scientific development of the awardee. In addition, the awardee must submit assurance of his/her intention to return to at least 75 percent effort as soon as possible. During the period of reduced effort, the salary and other costs supported by the award will be reduced accordingly. See: **NOT-OD-09-036.**

E. Changes in Research or Career Development Program: Consultation with the applicable NIH funding Institute or Center Program staff is strongly encouraged when a change in the approved career development program and/or research plan is being considered.

Individual awards are made for career development in a specific research program. A change in the specified scientific area of the research component of the career development program requires prior approval of the awarding NIH Institute or Center. A scientific rationale must be provided for any proposed changes in the aims of the original peer-reviewed research plan. The new research plan will be evaluated by staff of the awarding IC to ensure that the plan remains within the scope of the original peer-reviewed research program. If the new plan does not satisfy this requirement, staff could recommend that the award be terminated.

In rare cases where a mentor must be replaced, the institution must submit a letter from the proposed mentor and awardee documenting the need for substitution, the new mentor's qualifications for supervising the program, and the level of support for the PD/PI's continued career development. The letter must also document that the specific aims of the research program will remain within the scope of the original peer reviewed research program. Staff within the NIH funding component will review the request and will notify the institution of the results of the evaluation.

F. Change of Institution or Termination: Consultation with the applicable NIH funding Institute or Center program and/or grants management staff is strongly encouraged when either termination or a change of institution is being considered.

A change of grantee institution normally will be permitted only when all of the benefits attributable to the original grant can be transferred, including equipment purchased in whole or in part with grant funds. In reviewing a request to transfer a grant, NIH will consider whether there is a continued need for the grant-supported project or activity and the impact of any proposed changes in the scope of the project. A change may be made without peer review, provided the PD/PI plans no significant change in research and career development objectives and the facilities and resources at the new organization will allow for successful performance of the project. If these conditions or other programmatic or administrative requirements are not met, the NIH awarding office may require peer review or may disapprove the request and, if appropriate, terminate the award.

If the K awardee is moving to another eligible institution, career award support may be continued provided:

- A relinquishing statement is submitted by the original institution and a transfer application is submitted by the new institution at least three months prior to the transfer in order to allow the necessary time for administrative review by the NIH awarding Institute or Center.
- The awardee must establish in the transfer application that the specific aims of the research program to be conducted at the new institution are within the scope of the original peer-reviewed research program, and that a new mentor has been identified who has the appropriate research expertise and support to provide adequate guidance to the awardee and research support for the awardee's research program.
- All conditions of the award are met at the new institution.
- The period of support requested is no more than the time remaining within the existing award.

When a grantee institution plans to terminate an award, the Grants Management Specialist listed on the Notice of Award (NoA) must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination. The Director of the NIH awarding component may terminate an award upon determination that the purpose or terms of the award are not being fulfilled. In the event an award is terminated, NIH shall notify the grantee institution in writing of this determination, the reasons, the effective date, and the right to appeal the decision.

3. Reporting

When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the *NIH Grants Policy Statement.* (Note that the instructions for Research Career Development applications must be followed for this program).

The Progress Report must include Sections (A) through (F) as described in Section 2.2.6 (Progress Report Summary) in the general PHS form 2590 instructions, as well as sections “G” through “J” as described in Section 5 of the 2590 instructions. Evaluation of the awardee’s progress will encompass the following:

- A demonstration of scientific progress toward achieving the aims of the research as described in a brief summary of the studies and results obtained during the prior funding period;
- A description of career development and research-related activities undertaken during the prior funding period.
- A list of accomplishments such as publications, scientific presentation, new collaborations, inventions, or project-generated resources made during the prior funding period;
- A brief explanation of plans to address the specific aims during the next year of support;
- A description of proposed career development and research-related activities for the next year of support with a clear indication of percent effort devoted to research/research training and other activities.

- An annual evaluation statement of the candidate's progress by the mentor, as required in the PHS 2590 continuation application instructions (item J. Mentor's Report).

A final progress report, invention statement, and Financial Status Report are required when an award is relinquished when a recipient changes institutions or when an award is terminated.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research (program), peer review, and financial or grants management issues:

1. Scientific/Research Contact(s):

Candidates should refer to the Table of Institute and Center Contacts for information regarding each IC's scientific/research contact for this program.

2. Peer Review Contact(s):

Not Applicable

3. Financial/Grants Management Contact(s):

Candidates should refer to the Table of Institute and Center Contacts for information regarding each IC's grants management contact for this program.

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:
Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf) as mandated by the Health Research Extension Act of 1985 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm), and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) as applicable.

Human Subjects Protection:

Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants ("NIH Policy for Data and Safety Monitoring," *NIH Guide for Grants and Contracts*, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Sharing Research Data:

Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing). Investigators should seek guidance from their institutions, on issues related to institutional policies and local institutional review board (IRB) rules, as well as local, State and Federal laws and regulations, including the Privacy Rule.

Policy for Genome-Wide Association Studies (GWAS):

NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088. For additional information, see http://grants.nih.gov/grants/gwas/

Sharing of Model Organisms:

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh-Dole Act (see the *NIH Grants Policy Statement*. Beginning October 1, 2004, all investigators submitting an NIH application or contract proposal are expected to

include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Access to Research Data through the Freedom of Information Act:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are: (1) first produced in a project that is supported in whole or in part with Federal funds; and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the SF424 (R&R) application; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical

research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

Required Education on the Protection of Human Subject Participants:

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

Human Embryonic Stem Cells (hESC):

Criteria for Federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-116.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (http://escr.nih.gov/). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research.

NIH Public Access Policy Requirement:

In accordance with the NIH Public Access Policy, *investigators funded by the NIH must submit or have submitted for them to the National Library of Medicine's PubMed Central* (see http://www.pubmedcentral.nih.gov/), *an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication.* The NIH Public Access Policy is available at (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html). For more information, see the Public Access webpage at http://publicaccess.nih.gov/.

Standards for Privacy of Individually Identifiable Health Information:

The Department of Health and Human Services (HHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the HHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants,

cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs in NIH Grant Applications or Appendices:

All applications and proposals for NIH funding must be self-contained within specified page limitations. For publications listed in the appendix and/or Progress report, Internet addresses (URLs) or PubMed Central (PMC) submission identification numbers must be used for publicly accessible on-line journal articles. Publicly accessible on-line journal articles or PMC articles/manuscripts accepted for publication that are directly relevant to the project may be included **only** as **URLs** or **PMC submission identification numbers** accompanying the full reference in either the Bibliography & References Cited section, the Progress Report Publication List section, or the Biographical Sketch section of the NIH grant application. A URL or PMC submission identification number citation may be repeated in each of these sections as appropriate. There is no limit to the number of URLs or PMC submission identification numbers that can be cited.

Healthy People 2010:

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This FOA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

Authority and Regulations:

This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement*.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Loan Repayment Programs:

NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of

student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: http://www.lrp.nih.gov/.